

6741.US.O1

**Remarks**

This Amendment and Response is in reply to the Office Action mailed August 4, 2003 in the subject application.

Claims 1-16 are pending, with claim 16 being newly added.

**Rejections under 35 USC 112, paragraph 2**

Claims 1-15 have been rejected in the Office Action for indefiniteness for failure to particularly point out and distinctly claim the subject matter Applicants consider to be their invention.

As indicated above, several of these claims have been amended along the lines suggested by the examiner, though Applicants disagree that the claims as originally presented were indefinite. Other clarifying amendments were made to the claims. No new subject matter was introduced by any of these amendments.

Applicants particularly note that the expression "bPTH/80" would be clear to those skilled in the art, even if the examiner was confused by the terminology, to mean baseline PTH **divided by 80**, **not** baseline PTH equals 80, as the examiner has suggested.

With respect to the examiner's rejection of claims 11, 12 and 14, the Office Action incorrectly states that these claims "depend directly or indirectly from claim 7." A careful review of these claims establishes that these are independent claims; they do not in fact depend from claim 7 or any other claim. Hence the rationale offered in the Office Action for the indefiniteness rejection does not make sense as to these claims. Therefore, this rejection is improper and should be withdrawn.

6741.US.O1

**Prior Art Rejections**

Claims 1 and 2 stand rejected as anticipated by Cummings (US 5891868). The Office Action states that Cummings teaches the various steps of Applicants' claimed invention.

Applicants strongly disagree.

A careful reading of the claims in the subject application indicates that the Cummings patent is irrelevant to the patentability of Applicants' invention. Each of the independent claims (as amended above) makes this plain. For example, claim 1 begins with a preamble which states:

1. "A method of determining the initial dose of a vitamin D compound for the treatment of secondary hyperparathyroidism and renal osteodystrophy without increasing the incidence of hypercalcemia..."

No one skilled in the art would read Cummings to teach anything about a method for determining the initial dose of a Vitamin D compound. Instead, it is absolutely clear that Cummings relates to "methods for treating physical conditions resulting from postmenopausal estrogen decline in a postmenopausal subject." (See the abstract). Moreover, Column 4, lines 1-10 of Cummings state:

"The present inventors have also unexpectedly discovered that the treatment of physical conditions resulting from estrogen decline can be affected by ultra low doses of estrogen without the need for administration of progestin. "

Cummings does nothing more than make reference to following serum Vitamin D in the patients who were given multi vitamins containing Vitamin d in order to identify risks bone fractures. The examiner's attention is drawn to Cummings at column 3, lines 35-45, and especially lines 43-45 which state:

"In addition, low serum levels of 1,25 (OH)<sub>2</sub> Vitamin D levels also leads to increased risk of hip fractures."

6741.US.O1

With respect to other independent claims, Applicants also disagree that Cummings provides any relevant teaching for "treatments of secondary hyperparathyroidism and renal dystrophy without increasing the incidence of hypercalcemia" (claim 6), method of treating elevated PTH in a patient commencing treatment for end stage renal disease" (claim 7), "method of treating a patient for end stage renal disease using a vitamin D therapy (claim 10).

The rejection of Applicants' claimed invention over Cummings is improper and should be withdrawn.

Claims 1-15 stand rejected as obvious over the combined teachings of Cummings and Knutson (U.S. 5602116).

As indicated above, Cummings completely fails to teach any methods relevant to Applicants' claimed invention. Applicants further disagree with other statements in the Office Action, as follows.

The office action states that "Cummings discloses that low serum level of vitamin D compounds leads to bone loss disorders (column 2, lines 43-45). In fact, these lines do not state this, but instead state the following:

"Post menopausal subject" refers to women in the period of life after menopause. Subjects afflicted with post-menopausal symptoms include women after menopause who exhibit any of the foregoing physical conditions after menopause, and particularly women after menopause who have exhibited decreased bone mineral density, in the vertebrae, hip or other site or who have experienced wither vertebral or hip fracture."

The statement in the Office Action clearly is not factually based upon the cited passage.

With respect to the proposed combination of Cummings and Knutson, Applicants note that even if the examiner has correctly analyzed the teachings of

6741.US.01

Knutson, Knutson does not compensate for the deficiencies pointed out above with respect to Cummings.

Thus, the rejection is insufficient to render Applicants' invention as presently claimed obvious. The rejection should therefore be withdrawn.

### Conclusion

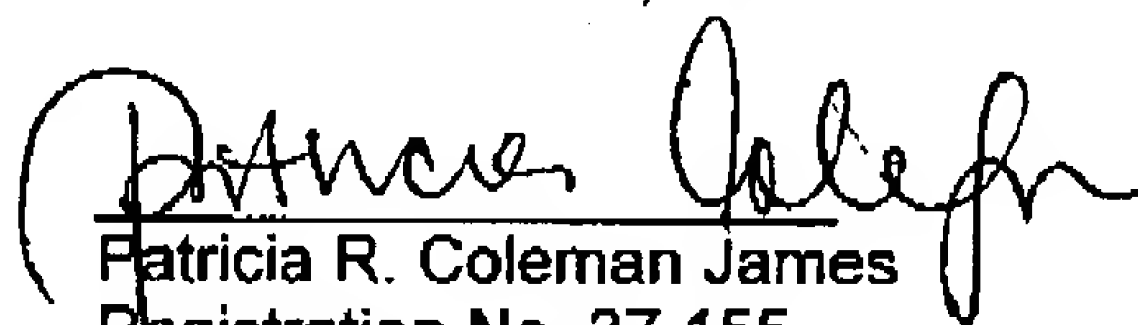
Applicants respectfully submit that the subject application is in condition for allowance and prompt allowance thereof is respectfully requested.

The examiner is urged to telephone the undersigned at 847 937 4558 to facilitate resolution of any remaining issues so that the subject application can be processed for allowance promptly.

**23492**

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23492	7590	06/25/2004	EXAMINER	
STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			LY, CHEYNE D	
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			1631	
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Please find below and/or attached an Office communication concerning this application or proceeding.

*Respectfully*

DUE DATE 7/25/04

DEADLINE DATE 12/25/04

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EXAMINER

ART UNIT

PAPER

060104

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

## Commissioner for Patents

The reply filed on February 13, 2004 is not proper because of the following omission(s) or matter(s): The claim amendments, filed on February 13, 2004, are improper due to being single spaced. Claim spacing must be either 1 ½ or double spaced (MPEP § 608.01(m) and 37 CFR §1.52(b)(2)(i). See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly  
6/20/04

*Ardin H. Marschel* 6/22/04  
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PRIMARY EXAMINER